APPENDIX A: METHODOLOGY

The literature search was conducted by the AHFMR Research Librarian between May 5, 2004 and June 1, 2004. Major electronic databases used include: The Cochrane Library, NHS Centre for Reviews and Dissemination (CRD Databases: NHS EED, HTA, DARE), PubMed, EMBASE, CINAHL. In addition relevant library collections, web sites of practice guidelines, regulatory agencies, evidence-based resources and other HTA related agency resources (AETMIS, CCOHTA, ECRI) were searched. Internet search engines were also used to locate grey literature.

Medical Subject Headings (MeSH) relevant to this topic are: Laser therapy, low-level; Wound healing; Decubitus ulcer; Diabetic foot; Foot ulcer; Leg ulcer; Skin care

Other keywords used: sores, ulcers, wounds, lasers, biostimulation. Variations of keywords were used alone or in combinations in the following electronic databases and websites.

Database	Platform or URL	Search Terms
Cochrane Library: Cochrane Collaboration	Licensed for use	LASERS single term (MeSH) AND wound* or ulcer* or sore*
PubMed: National Library of Medicine	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?holding=icauahslib	Lasers OR low level laser OR LLLT OR biostimulation AND wound healing or wound OR wounds OR ulcer OR ulcers OR decubitus ulcer OR skin disease OR bedsores OR skin care OR diabetic foot OR skin ulcer OR skin OR leg ulcer NOT Animals OR animal AND Systematic (sb) OR limit to Clinical Trial OR Meta-Analysis OR Practice Guideline OR review Limits: publication date from 1998
NHS Centre for Reviews and Dissemination (CRD) Databases: HTA, EED, DARE	http://nhwcrd.york.ac.uk	Laser and wound or sore or ulcer
ECRI's HTAIS resources	http://www.ecri.org	Laser o r lasers AND Wound OR ulcer OR sore

Database	Platform or URL	Search Terms
EMBASE (1996 to 2004, Week 19)	Licensed for use: OVID technologies interface	1 exp laser/ 2 exp Wound/ 3 exp Ulcer/ 4 exp Decubitus/ 5 exp diabetic foot/ 6 1 and (2 or 3 or 4 or 5) 7 limit 6 to yr=1998 – 2004 8 low level.mp. 9 low intensity.mp. 10 low power.mp. 11 lllt.mp. 12 laser$ therap$.mp. 13 7 and (8 or 9 or 10 or 11 or 12) 74 hits
NEOS (Central Alberta Library Consortium)	http://www.library.ualberta.ca/catalogue	Laser? AND Wound? OR sore? OR ulcer? OR skin
Canadian Task Force on Preventative Healthcare	http://www.ctfphc.org/	Laser OR lasers
Cabot	http://cahspr.ca/cabot/	Database not available
CINAHL (1982 to April 2004 Week 5)	OVID	1 exp lasers/ 2 exp wound healing/ OR exp pressure ulcer/ 3 exp skin ulcer/ OR exp foot ulcer/ OR exp ulcer/ OR exp leg ulcer. 4 exp wound care/ OR exp diabetic foot/ 5 exp Necrosis/ 6 exp wounds and injuries/ 7 1 and (2 or 3 or 4 or 5 or 6) 8 limit 7 to yr = 1998 – 2004 = 64 hits
AETMIS	http://www.aetmis.gouv.qc.ca	Laser OR lasers = 0 relevant
Health Quality Council, Saskatchewan	http://www.hqc.sk.ca/	Laser OR lasers = 0 relevant
Institute for Clinical and Evaluative Sciences (ICES), Ontario	http://wwwices.on.ca/	Laser OR lasers = 0 relevant
CCOHTA	http://www.ccohta.ca/publications/pubs_e.asp	Laser OR lasers – 0 relevant
CMA Infobase	http://wwmdm.ca/cpgsnew/cpgs/index.asp	Lasers OR laser

Database	Platform or URL	Search Terms
National Guideline Clearinghouse	http://www.guideline.gov	Laser AND Wound* OR sore* OR ulcer*
Health Canada-Medical Devices Active License Listing	http://www.mdall.ca/	Device name: laser, lasers, low level laser
US Food and Drug Administraion (FDA) – Center for Devices and Radiological Health/CDRH	http://www.fda.gov/cdrh/	Product codes: LLP ILY, NHN
Clinical Trials.gov (US)	http://clinicaltrials.gov/	Laser OR lasers AND Sore or sound or ulcer = 0 relevant
Center Watch Clinical Trials Listing Service	http://www.centerwatch.com/	Trial listing browsed – 0 relevant
World Wide Web Search Engines: • Google • Alltheweb	 www.google.com www.alltheweb.com	 Low level laser wound healing hta

Note:
Truncation: The * symbol is a truncation character that retrieves possible suffix variations of the root word e.g. surg* retrieves surgery, surgical, surgeon, etc. In databases accessed via the OVID platform the truncation character is $;

Limits (where available): Searches were limited to human; publication dates: 1999 and 2004.

Publication types and number of studies found (Table 1):

- Randomized controlled clinical trials 6 (1 multicentre)
- Controlled clinical trials 0
- Non-controlled clinical trials 3
- Prospective comparative studies 0
- Retrospective studies 0

Jovell and Navarro-Rubio [29] published a classification scheme that comments on quality of evidence that a previous health technology assessment employed was used in this report for comparison purposes [1]. Assignment to categories is dependent on conditions of scientific rigour. This scheme forms the basis of the classification of studies in Table 1 into the following categories:

Good: Meta-analysis of randomized controlled trials (RCTs) or from large sample RCTs;

Good to Fair: Small sample RCTs and non-randomized controlled prospective trials;

Fair: Non-randomized controlled retrospective trials, cohort studies and case-control studies;

Poor: Non-controlled clinical series and various other approaches.

In this health technology assessment:

Efficacy refers to the performance of a technology under 'ideal' conditions or conditions of best practice; and

Effectiveness refers to the performance of a technology under 'routine' conditions. For example when it has become widely distributed in a health care system.

APPENDIX B: NPUAP STAGING CRITERIA

In the current literature, the National Pressure Ulcer Advisory Panel (NPUAP) staging system from the 1989 Consensus Development Conference is cited more frequently than others for the staging of pressure sores [30]. This staging system has been adopted by the Agency for Health Care Policy and Research (AHCPR) Pressure Ulcer Guideline Panels and is published in both sets of AHCPR (now AHRQ) Pressure Ulcer Clinical Practice Guidelines (1992, 1994). It is described as follows:

Stage 1

Pressure ulcer is an observable pressure-related alteration of intact skin whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel), and/or sensation (pain, itching).

The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.

Stage 2

Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

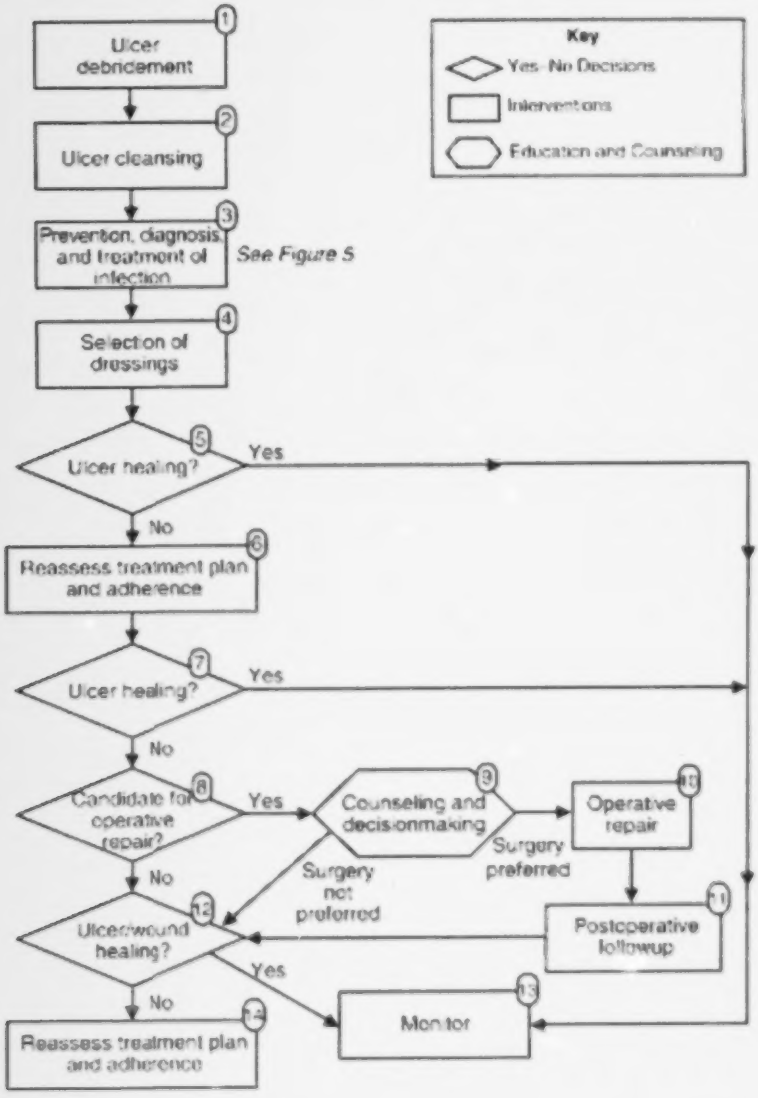
Stage 3

Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage 4

Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint, capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Appendix C: AHCPR Supported Clinical Practice Guidelines for the Treatment of Pressure Ulcers



Source: [31]

APPENDIX D: CANADIAN ASSOCIATION OF WOUND CARE RECOMMENDATIONS FOR PRACTICE

Prevention & Treatment of Venous Leg Ulcers Prevention & Treatment of Venous Leg Ulcers

1. A careful history is required to determine the venous disease characteristics and rule out other diagnoses. It is important to assess pain and identify the systemic and local factors that may impair wound healing.
2. Determine the cause of chronic venous insufficiency (CVI): abnormal valves, DVT or obstruction, or calf muscle pump failure.
3. The ankle-brachial index is an important test to perform in all patients with venous ulcers.
4. Assess for infection and treat if indicated.
5. It is important to communicate with the patient, the family, and the caregivers to establish realistic expectations for healing.
6. High compression bandaging should be used in the absence of arterial disease for the management of venous edema.
7. Graduated compression stockings must be worn for the prevention of venous edema and venous leg ulcer recurrence.
8. Intermittent pneumatic compression therapy can be used as an adjunctive therapy in the management of venous edema and venous leg ulcers.
9. Rehabilitation consult as indicated for to maximize activity and mobility.
10. Optimize the local wound healing environment: debridement, bacterial balance and moisture balance. Use biological agents when the cause has been corrected and healing does not proceed at an expected rate.
11. If significant superficial or perforator vein disease exists, surgical management should be considered.
12. The presence or absence of a social support system is important for treatment and, in the end, prevention.

Recommendations for Practice: Prevention & Treatment of Diabetic Foot Ulcers

1. Persons with diabetes (PWD) must be aware of the risks to their feet associated with diabetes. Take a careful history to determine general health, diabetic control and complications. PWDs should always remove their shoes and socks when visiting a health-care professional.
2. Persons with diabetes (PWD), caregivers and health-care professionals should recognize that loss of protective sensation (LOPS) is the greatest risk factor for the development of plantar ulcers.
3. Classify persons with diabetes (PWD) into a risk category to allow co-ordination of treatment and follow-up. Recognize that adequate vascular supply must be determined for healability.
4. Provide pressure downloading if there is LOPS.
5. Provide access to appropriate foot-care teaching and professional care as indicated by patient need and by risk category.
6. Classify plantar ulcerations according to a category.
7. Provide an optimum wound environment (debridement, moisture balance, infection control). If healability is not established, moist interactive healing and aggressive debridement is not recommended.
8. Assess and treat for infection when indicated.
9. Identify and modify patient-related co-factors.
10. Establish and empower a 'TEAM' to work with patients with diabetes.

Recommendations for Practice: Prevention & Treatment of Pressure Ulcers

1. Complete client history and physical examination to determine general health and risk factors that may affect healing. Risk assessment tools offer the clinician a significant evaluative tool and should be used and recorded at initial assessment and subsequent periodic examinations.
2. Assess current sitting and recumbent pressure management techniques and devices. Provide pressure reduction or relief as required.
3. Assess and control pain. Analgesia should be provided to control the pain in anticipation of an intervention as well as for maintaining control of acute nonincident or chronic pain.
4. Maximize nutritional status. The level of nutrition should be compatible with the client's and/or family's wishes and a Nutritional Screening/Assessment should be completed.

5. Control moisture and incontinence.
6. Maximize activity and mobility and reduce or eliminate friction and shear.
7. Assess and assist with psychosocial needs. Ultimately the aims of therapy should be to relieve suffering and provide as efficiently and efficaciously as possible a healed wound.
8. Provide an optimal wound environment. Use clinical judgement to select a type of moist wound dressing suitable for an ulcer.
9. Infection control: Assess bioburden management, r/o or treat infection.
10. Introduce adjunctive modalities as required.
11. Develop a multidisciplinary team specific to the needs of the client: Best practice carried out by a dedicated wound team is the most reliable means of providing improved outcomes in pressure ulcer management.
12. Educate client and care givers re: the prevention and treatment of pressure ulcers.

Sources: [26-28]